K003543

JUN - 5 2001

stryker® INSTRUMENTS

4100 East Milham Avenue
Kalamazoo, MI 49001
Phone (616) 323-7700
(800) 253-3210

Device Name:

Trade Name:	Stryker PainPump II
Common Name:	Electromechanical Ambulatory Infusion Pump
Classification Name:	Pump, Infusion, PCA : 21 CFR 880.5725, Class II

Device Sponsor:

Manufacturer:	Stryker Corporation Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 Registration No.: 1811755

Regulatory Class: Class II

Summary of Safety and Effectiveness:

The Stryker PainPump II is intended an electromechanical pump which delivers a controlled amount of medication to the patient for the purpose of managing pain. The pump delivers medication using one or both of the following drug delivery profiles: an hourly flow rate and a bolus PCA (patient controlled anesthetic) dosing option. Routes of administration may be intraoperative, subcutaneous or percutaneous. Dosage rates and patient lock out times are programmed into the PainPump II unit by the physician.

The PainPump II is contraindicated for infusion of blood and blood products, insulin, or life-supporting medication.

The Stryker PainPump II is a kit that is comprised of an electromechanical infusion pump, an infusion set, and an introducer needle.

The Stryker PainPump II infusion pump is equivalent in intended use, safety, and effectiveness to existing infusion pump systems being marketed by companies such as CADD Legacy, Arrow, and McKinley Medical.

The Stryker PainPump II catheters are equivalent in intended use, safety, and effectiveness to existing catheters being marketed by companies such as I-Flow and Sims Portex.

The Stryker PainPump II introducer needles are equivalent in intended use, safety, and effectiveness to existing needles being marketed by companies such as TFX Medical and Avid NIT.

The Stryker PainPump II does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker PainPump II is substantially equivalent to these existing devices.

By: Nicole Petty
Nicole Petty
Regulatory Analyst

Dated: 3-8-01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2001

Ms. Nicole Petty
Regulatory Analyst
Stryker Instruments
Instruments Division
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K003543
Trade/Device Name: Stryker PainPump II
Regulation Number: 880.5725
Regulatory Class: II
Product Code: FRN
Dated: March 8, 2001
Received: March 12, 2001

Dear Ms. Petty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K003543

Device Name: Stryker PainPump II

Indications For Use:

PainPump II is an electromechanical pump which delivers a controlled amount of medication to the patient for the purpose of managing pain. The pump delivers medication using one or both of the following drug delivery profiles: an hourly flow rate and a bolus PCA (patient controlled anesthetic) dosing option. Routes of administration may be intraoperative, subcutaneous or percutaneous. Dosage rates and patient lock out times are programmed into the PainPump II unit by the physician.

The PainPump II is contraindicated for infusion of blood and blood products, insulin, or life-supporting medication.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The- Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cucuzzo

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003543